

REMARKS

Claims 1-16 were pending. Claim 1-8 and 16 were canceled. Claim 9-15 were amended and new claims 17-25 were added.

Objections to the Specification

The specification was objected to for misspellings of the word "unexpectedly". The specification has been amended to correct these misspellings at page 2, line 23 and page 5, line 15 and 23, as well as on page 4, line 5 and page 6, line 21. Additionally, the misspelling of the word "highlights" was corrected on page 4, line 19.

Rejections Under 35 USC§112, ¶ 2

Claims 3, 5, 9, 15-16 were rejected for alleged indefiniteness. These rejections have all been rendered moot by the claims amendments. The claims as amended are believed to be in full compliance with section 112.

Rejections Under 35 USC§102(b)

Claims 1-7, 9 and 16 were rejected for alleged anticipation by Lopresti et al, J. Clin. Endocrin. And Metab., Vol 73, No. 4, 1992, pages 703-709 ("Lopresti"). The examiner found that Lopresti disclosed administration of triiodothyronine sulfate (T3S) to human volunteers.

However, Lopresti does not disclose the currently claimed methods, compositions or kits, which all require oral administration of T3S. Indeed, Lopresti reports intravenous injection (either as a bolus or a constant infusion) of labeled T3S (T3S labeled with ¹²⁵I) to volunteers. In addition, in order to determine whether oral absorption was occurring, T3S labeled with ¹²⁵I was orally administered. See p. 704, right column paragraph 4. Lopresti found that no absorption of the labeled T3S was detected. See Abstract. Thus, Lopresti does not disclose the claimed compositions, kits and methods of treatment in which T3S is orally administered.

Rejections Under 35 USC§103(a)

Claims 8 and 10-15 were rejected for alleged obviousness over Lopresti in view of Larsen et al US 5,272,078 ("Larsen"). The examiner found that Lopresti failed to teach (i) the

amount of T3S in the composition (claims 10-15); (ii) T3S formulation with thyroxine (claims 8 and 13-15); (iii) the amount of thyroxine in the composition (claims 13-15); and (iv) the pharmaceutical composition in a kit. The examiner asserted that these missing elements would have obvious to the skilled artisan.

However, as explained above, Lopresti fails to disclose oral administration of T3S to treat pathologies associated with decreased production or activity of thyroid hormones. Indeed, Lopresti confirms the expectation of the skilled artisan that T3S would not be absorbed by the GI tract given that it bears the highly polarized/ionic group $-\text{OSO}_3\text{H}$:

No labeled T3S was detected in the serum of patients after oral ingestion of $[^{125}\text{I}]\text{T3S}$. Serial urine collections in one subject revealed that 5.4% of the ingested tracer was excreted in 24h and 10.4% was excreted in 72 h (Fig 3). In contrast, the oral administration of $[^{131}\text{I}]\text{Na}$ demonstrated 75% excretion by 24 h and 93% by 72 h.

p.707, left column first paragraph. See also p. 708, right column, first paragraph. Thus, Lopresti neither suggests nor discloses the claimed invention, and in fact teaches away from the claimed methods.

Larsen does not remedy this deficiency. Larsen "is directed to the cloning, sequencing and uses of a nucleotide sequence according the mammalian enzyme Type I iodothyronine 5' deiodinase and mutant sequences thereof". See Abstract. Larsen neither teaches nor suggests oral administration of T3S, alone or in association with thyroxine.

Thus, prior art neither teaches nor suggests that T3S could be sufficiently absorbed by the GI system to permit its use as an oral thyromimetic drug. Indeed, it suggests the opposite. Consequently none of the cited references alone or in combination teaches or suggests the claimed invention.

CONCLUSION

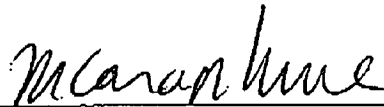
In view of the preceding remarks, it is believed that claims 9-15, and 17-25 are in condition for allowance.

No fee is believed to be due with the filing of this Amendment. However, if any fees are deemed necessary, the Director is hereby authorized to charge such fees to Deposit Account No. 50-2168.

Favorable action is respectfully requested.

Respectfully submitted,

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